IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, NORTH CAROLINA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* CATHLEEN FORNEY, | : | CIVIL ACTION NO. 15-6264 |
| Plaintiffs/Relator, | : | |
| v. | : | |
| MEDTRONIC, INC., | : | |
| Defendant. | : | |

**MEMORANDUM OPINION**

Smith, J. June 4, 2018

In this case, the relator contends that the defendant, a medical device company, paid kickbacks to health care providers in violation of the False Claims Act. The False Claims Act, however, includes a public disclosure bar that prohibits lawsuits brought by relators where the relator's allegations of fraud have already been disclosed to the government. The company contends that the claims of fraud raised in the relator's complaint were publicly disclosed prior to the time the relator filed the complaint. Consequently, the company asks the court to enter summary judgment in its favor and dismiss the action under the public disclosure bar.

The company's motion, however, presents numerous technical legal issues, several of which have yet to be resolved in this circuit. A number of these issues arise from the fact that in 2010, as part of the Patient Protection and Affordable Care Act, Congress amended the public disclosure bar to restrict the material that counts as a public disclosure and broadened the exception to the public disclosure bar. The exception now provides, in broad terms, that a relator may avoid dismissal under the bar if she is an original source. While the Third Circuit has had occasion to address the post amendment disclosure bar, the parties, through the outstanding work of counsel, have raised a number of creative arguments that the Third Circuit has yet to address.

In addition to those unresolved legal questions, the motion also presents difficult factual issues. The public disclosure bar analysis involves an intricate comparison of the fraud allegations in this case to the fraud allegations in the prior public disclosures. After performing this comparison, the court must also address the original source exception. In an effort to solidify her status as an original source, the relator has submitted over two thousand pages of documents to the court.

After reviewing the amended public disclosure bar and the applicable case law, the court concludes that the vast majority of the relator's allegations of fraud were contained in valid prior public disclosures. The court also finds, however—after a rigorous examination of the documents the relator provided to the government—that under the Third Circuit's interpretation of the original source exception, the relator qualifies as an original source. Thus, despite the presence of prior public disclosures that advanced substantially the same allegations of fraud as the relator does here, the court denies the motion for summary judgment.

## I. PROCEDURAL HISTORY

On November 20, 2015, the relator, Cathleen Forney ("Relator Forney"), filed a sealed complaint alleging that the defendant, Medtronic, Inc. ("Medtronic"), violated the federal False Claims Act ("FCA"). Doc. No. 1. Relator Forney named the United States and 29 state governments as plaintiffs in the action. *See* Compl. at 1, Doc. No. 1. The United States then filed two motions seeking to extend the seal while it determined whether to intervene in the case. Doc. Nos. 2, 6. The court granted both motions and extended the seal. Doc. Nos. 3, 7. Then, on December 12, 2016, the United States and the 29 plaintiff states filed notices that they declined intervene. Doc. Nos. 8, 9. Accordingly, on December 14, 2016, the court lifted the seal and ordered Relator Forney to serve the complaint on Medtronic. *See* Dec. 14, 2016 Order, Doc. No. 11.

Four months later, Relator Forney filed an amended complaint. Doc. No. 17. The court ordered Medtronic to respond to the amended complaint by April 24, 2017. *See* April 13, 2017 Order, Doc. No. 29. On April 24, 2017, Medtronic filed a motion to dismiss the amended complaint in which it asserted, *inter alia*, that Relator Forney had failed to plead fraud with sufficient particularity. *See* Def. Medtronic, Inc.'s Mem. of Law in Supp. of Its Mot. to Dismiss, Doc. No. 30-1; *see* Fed. R. Civ. P. Rule 9(b) (requiring fraud to be pled with particularity). The court found serious problems with the allegations in the amended complaint and, accordingly, granted the motion and dismissed the amended complaint without prejudice. *See* June 19, 2017 Mem. Op., Doc. No. 37; June 19, 2017 Order, Doc. No. 38.

Relator Forney then filed a second amended complaint on July 6, 2017. Doc. No. 42. On July 27, 2017, Medtronic moved to dismiss the second amended complaint. Doc. No. 48. On August 14, 2017, notwithstanding the court's lingering concern that the "relator's theory of

support services amounting to illegal remuneration will not ultimately prove to be viable," the court denied the second motion to dismiss "without prejudice to the defendant raising its arguments in a motion for summary judgment." Aug. 14, 2017 Order, Doc. No. 52. Accordingly, the court set scheduling deadlines and ordered the parties to complete fact discovery by December 22, 2017. Aug. 14, 2017 Scheduling Order, Doc. No. 51.

Prior to the conclusion of fact discovery, Medtronic filed an early motion for summary judgment. *See* Def. Medtronic Inc.'s Mot. for Summ. J. Due to Public Disclosure Bar ("Def.'s Mot."), Doc. No. 64. In the motion, Medtronic contends that it is entitled to summary judgment in its favor because of the FCA's public disclosure bar. *See id.* Accordingly, the court placed all scheduling deadlines in suspense pending resolution of the motion for summary judgment. *See* Nov. 29, 2017 Order, Doc. No. 67. Relator Forney filed a response to the motion on December 8, 2017, and Medtronic filed a reply in further support of the motion on December 20, 2017. Doc. Nos. 69, 70. On December 20, 2017, the court heard oral argument on the motion for summary judgment.

The court ordered supplemental briefing on April 3, 2018. *See* Apr. 3, 2018 Order, Doc. No. 74. Relator Forney filed a supplemental memorandum on April 17, 2018. Doc. No. 75. Medtronic filed a response to the supplemental memorandum on May 1, 2018. Doc. No. 76. The motion for summary judgment is now ripe for adjudication.

## II. FACTUAL BACKGROUND

The second amended complaint sets forth the following allegations: Medtronic is a massive international medical device manufacturer that, in the United States alone, "generate[s] between 8.8 and 9.2 billion dollars per year." Second Am. Compl. at 4, Doc. No. 42. Relator Forney worked at Medtronic for 16 years—from 1996 until 2012 when Medtronic terminated her

employment. *See id.* at 2. At the time of her termination, Relator Forney was working as a District Service Manager for the Cardio and Vascular Group, where she reported to the District Manager for the Eastern Pennsylvania District. *See id.* at 2, 4.

Relator Forney contends that during her time at Medtronic she observed Medtronic engage in an extensive illegal fraud scheme. *See id.* at 1–2, 4. In broad terms, she contends that Medtronic provided free services to people "who made purchasing decisions about Medtronic devices" and that these free services were "intended to persuade health care providers to purchase Medtronic devices." *Id.* at 4. Relator Forney contends that these services constitute illegal remuneration under the FCA. *See id.* at 15.

Relator Forney references a number of instances where Medtronic allegedly provided services as an incentive to convince health care providers to purchase devices from it. These instances can be grouped into three categories: (1) device checks and device interrogations; (2) implant services; and (3) practice management consulting. *See* Second Am. Compl. at 4–19; *see also* Relator Forney's Opp. to Medtronic's Mot. for Summ. J. Based on Public Disclosure Bar at 19 ("Forney's Br.") (characterizing the second amended complaint as alleging these three theories of fraud), Doc. No. 69-1. Relator Forney is apparently no longer pursuing her implant services theory. *See* Forney's Br. at 19 n.3 ("Relator intends to seek only damages for kickbacks paid in the form of device checks and consulting services. Relator has conferred with the United States, which does not object to Relator ceasing to prosecute the free labor at implant surgeries."). Accordingly, the court will address the remaining two theories in turn.

Beginning with Relator Forney's device check theory, she contends that after a physician implanted a Medtronic medical device, Medtronic provided "checks" or "interrogations" of the

device. *See* Second Am. Compl. at 9–10. Relator Forney offers her own experience and training as an example of these device checks:

> Ms. Forney was credentialed to perform the following services at one hospital: (1) performing system assessments on Pacemakers through the use of packing system analyzers and programmers, (2) evaluation and reprogramming of Pacemaker devices at bedside, evaluation and reprogramming of devices at bedside, (3) performing system assessments on ICD Systems through the use of system analyzers and programmers, (4) evaluation and reprogramming of ICD devices at bedsides, and (5) evaluation and reprogramming of IC [sic] devices at procedural and surgical suites off-site from hospitals.

*Id.* at 10. Relator Forney also contends that, in order to facilitate these free device checks, Medtronic paid "the necessary costs involved in credentialing" its Clinical Specialists. *Id.* at 11. These costs included background checks. *See id.* Costs of the background checks range from $60 to $250 each. *See id.* Relator Forney contends that this is a cost that the health care provider would have had to bear if Medtronic had not covered it. *See id.* Moreover, the Clinical Specialists themselves obviate the need for health care providers to require one additional staff member. *See id.* As stated by Relator Forney: "This free staff person eliminated the need of the hospital to pay to credential a staff member, as well as eliminating the need to hire the necessary staff." *Id.*

Turning to Relator Forney's practice management theory, Relator Forney alleges that

> Medtronic created an entire structure of 'lean sigma' training that taught Ms. Forney and others how to provide free consulting services as a means to integrate their services into the health care provider's practice management tasks. Medtronic offered free assistance on reimbursement, and free consulting on all sorts of practice management topics.

*Id.* at 13; *see also* Relator Forney's Opp. to Medtronic's Mot. for Summ. J. Based on Public Disclosure Bar, Ex. 1 at ECF pp. 23–29 (describing the lean sigma training / approach), Doc. No. 69-3. Under the umbrella of the practice management theory, Relator Forney raised two distinct

allegations of fraud.[1] First, Medtronic trained Clinical Specialists to handle administrative tasks that the health care provider would normally handle. *See* Second Am. Compl. at 11–12. For example, Relator Forney drafted a worksheet to track remote monitoring. *See id.* She also alleges she assisted health care providers with data entry: "Medtronic Clinical Specialists [entered] data [] into [] hospital databases maintained by St. Luke's Hospital and Lehigh Valley Hospital Muhlenberg." *Id.* (alterations to original). Relator Forney contends that "Medtronic [] directed its employees to engage in these clerical data-entry tasks as a means of providing value to the hospitals." *Id.* at 12 (alteration to original).

Second, Relator Forney contends that Medtronic provided free reimbursement guidance to health care providers. *See id.* at 12. Specifically, she alleges that "Medtronic taught health care providers how to increase profits by maximizing their revenue from government-funded health care programs." *Id.* In other words, Medtronic taught health care providers how to accurately code their reimbursement requests so that the health care providers were able to recover maximum reimbursement from government-sponsored health care programs. *See id.*

In sum, Relator Forney has alleged that Medtronic engaged in a nationwide scheme to provide free services to health care providers. Relator Forney contends that these free services are illegal kickbacks under the FCA. These free services included device checks and device interrogations provided by Medtronic Representatives. To facilitate these free checks, Medtronic paid to have its representatives credentialed—a cost that the health care provider would typically

[1] Relator Forney appears to argue in her opposition brief that these should be considered a single allegation of fraud, *i.e.*, that the entire lean sigma program was a fraudulent kickback. *See* Forney's Br. at 19. This argument is unsupported by the allegations in the second amended complaint. In the second amended complaint, Relator Forney alleged that each distinct service was an illegal kickback. *See* Second Am. Compl. at 18 ("Medtronic continues to provide kickbacks in the form of free surgical support, post-implant device interrogation and analysis, and consulting services, reimbursement services, and various other services of value to healthcare providers, such as data entry and practice management worksheets and the like.").

have paid. And finally, Medtronic also provided free administrative assistance and reimbursement guidance to health care providers.

## III. DISCUSSION

### A. Standard of Review – Motions for Summary Judgment

A district court "shall grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Additionally, "[s]ummary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Wright v. Corning,* 679 F.3d 101, 103 (3d Cir. 2012) (quoting *Orsatti v. New Jersey State Police,* 71 F.3d 480, 482 (3d Cir. 1995)). An issue of fact is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 248 (1986). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Id.*

The party moving for summary judgment has the initial burden "of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). Once the moving party has met this burden, the non-moving party must counter with "'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986) (citation omitted); *see* Fed. R. Civ. P. 56(c) (stating that "[a] party asserting that a fact . . . is genuinely disputed must support the assertion by . . . citing to particular parts of materials in

the record . . .; or . . . [by] showing that the materials cited do not establish the absence . . . of a genuine dispute" (alterations to original)). The non-movant must show more than the "mere existence of a scintilla of evidence" for elements on which the non-movant bears the burden of production. *Anderson*, 477 U.S. at 252 (1986). Bare assertions, conclusory allegations, or suspicions are insufficient to defeat summary judgment. *See Fireman's Ins. Co. v. DuFresne*, 676 F.2d 965, 969 (3d Cir. 1982) (indicating that a party opposing a motion for summary judgment may not "rely merely upon bare assertions, conclusory allegations or suspicions"); *Ridgewood Bd. of Educ. v. N.E. for M.E.*, 172 F.3d 238, 252 (3d Cir. 1999) (explaining that "speculation and conclusory allegations" do not satisfy non-moving party's duty to "set forth specific facts showing that a genuine issue of material fact exists and that a reasonable factfinder could rule in its favor"). Additionally, the non-moving party "cannot rely on unsupported allegations, but must go beyond pleadings and provide some evidence that would show that there exists a genuine issue for trial." *Jones v. United Parcel Serv.*, 214 F.3d 402, 407 (3d Cir. 2000). Moreover, arguments made in briefs "are not evidence and cannot by themselves create a factual dispute sufficient to defeat a summary judgment motion." *Jersey Cent. Power & Light Co. v. Township of Lacey*, 772 F.2d 1103, 1109–10 (3d Cir. 1985).

The court "may not weigh the evidence or make credibility determinations." *Boyle v. County of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998) (citing *Petruzzi's IGA Supermarkets., Inc. v. Darling–Del. Co. Inc.*, 998 F.2d 1224, 1230 (3d Cir. 1993)). Instead, "[w]hen considering whether there exist genuine issues of material fact, the court is required to examine the evidence of record in the light most favorable to the party opposing summary judgment, and resolve all reasonable inferences in that party's favor." *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). The court must decide "not whether . . . the evidence unmistakably favors one side or the other

but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." *Anderson*, 477 U.S. at 252. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial'" and the court should grant summary judgment in favor of the moving party. *Matsushita Elec. Indus. Co.*, 475 U.S. at 587 (citation omitted).

### B. Analysis

In its motion for summary judgment, Medtronic generally contends that the court should grant summary judgment under the FCA's public disclosure bar. The relevant portion of the FCA states:

> **(4)(A)** The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
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> **(i)** in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
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> **(ii)** in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> **(iii)** from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> **(B)** For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(A), (B) (footnote removed).[2] Per this portion of the FCA, a defendant seeking to have the court dismiss an action under the public disclosure bar must prove three elements: (1) a valid public disclosure exists; (2) the prior public disclosure revealed

[2] In 2010, Congress amended the FCA's public disclosure bar. The prior bar "stated that '[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions [in certain enumerated sections.]'" *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016) (quoting 31 U.S.C. § 3730(e)(4)(A) (2006)). Whereas courts interpreted the prior bar as a jurisdictional bar, "the amended version does not set forth a jurisdictional bar." *Id.* at 300 (citations omitted).

"substantially the same allegations or transactions" of fraud alleged in the present action; and (3) the relator is not an original source. *See U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 300–08 (3d Cir. 2016).

**1. The Relevant Material Facts**

As for the material facts relevant to resolving whether the public disclosure bar applies in this matter, the parties' submissions demonstrate that the material facts are not genuinely disputed. To determine which facts are material the court looks to the substantive law. There are two relevant legal inquires: (1) did any prior public disclosures allege substantially the same fraud alleged by Relator Forney, and if so, (2) did Relator Forney provide information to the government that materially added to these prior public disclosures? The facts that bear on these inquires can be lumped into three categories: (1) what allegations and / or transactions of fraud were disclosed in the prior public disclosures; (2) what allegations and / or transactions of fraud did Relator Forney allege in her second amended complaint; and (3) what information did Relator Forney provide to the government prior to filing this lawsuit. Because the court has already described Relator Forney's allegations in detail, the court will only address the first and third categories here.

Under the first category, Medtronic contends that five federal *qui tam* cases qualify as valid prior public disclosures.[3] As explained in more detail below, the court finds that two of the five potential prior public disclosures—*Onwezen* and *Schroeder*—satisfy the public disclosure standard. Beginning with *Onwezen*, *Onwezen* disclosed—in broad terms—that Medtronic was providing free device checks and interrogations:

[3] The five cases are: *United States ex rel. Burns v. Medtronic, Inc. et al.*, 10cv1851 (M.D. Fl.) ("*Burns*"); *United States ex rel. Onwezen et al. v. Medtronic, Inc.*, 7cv4777 (D. Minn.) ("*Onwezen*"); *United States ex. rel. Stokes et al.*, 11cv1082 (D.D.C.) ("*Stokes*"); *United States ex rel. Schroeder*, 9cv279 (E.D. Cal.) ("*Schroeder*"); *United States v. Doe I and Doe II*, 14cv8096 (D.N.J.) ("*Doe*").

> As part of its efforts to corner the market, [Medtronic] promises both doctors and hospitals that use Medtronic's cardiac rhythm devices that it will provide all follow-up care for those patients. Physicians often complain that checking the devices during their clinic times is time-consuming and expensive. As an incentive for doctors and hospitals to choose Medtronic devices, Medtronic Representatives tell doctors and hospitals that if they use a Medtronic device, they will not have to be involved in any of the patient's follow-up care. . . .
>
> [T]he implant of a Medtronic pacemaker or ICD is often the first and last time the implant patient will ever see the doctor. Instead nearly all follow-up visits, any telephone or other inquiries, and necessary adjustments or programming changes to the device, and medical questions will all be handled by a Medtronic Representative . . . .

Def.'s Mot. at Ex. E at ¶¶ 68, 70 (alterations to original), Doc. No. 64-9. *Onwezen* also alleged that the provision of these free device checks was an illegal kickback under the FCA. *See id.* at ECF p. 20 ("Defendant provides improper kickbacks in the form of medical services . . . ." (capitalization altered)).

Additionally, *Onwezen* disclosed that Medtronic was providing free reimbursement advice to health care providers. *See id.* at ¶ 75 ("Medtronic Representatives are trained to sit down with the doctor to show him how s/he is under-billing. They are instructed to point out to doctors that, in order to maximize profits, they should turn over all billing responsibilities to a Medtronic Representative."). Finally, *Onwezen* alleged that Medtronic provided free administrative work to health care providers: "Medtronic Representatives advise doctors that the Representatives will handle all of the paper-work related to billing for implant patients, including filling out the 'visit sheets' used by doctors to document the work they have purportedly done, and the 'billing sheets' submitted to Medicare." *Id.* at ¶ 79.

Similarly, *Schroeder* disclosed that Medtronic was providing free reimbursement guidance. Specifically, *Schroeder* alleged that "Medtronic [] directed sales representatives to educate physician staffs on how to bill Medicare, Medicaid and other insurers, in effect offering

unpaid work from Medtronic employees to doctor's offices." Def.'s Mot. at Ex. I at ¶ 51 (alteration to original), Doc. No. 64-13. *Schroeder* also disclosed that Medtronic was providing business consulting services to health care providers. *See id.* at ¶ 81 (alleging that Medtronic provided a "'turn-key' heart failure clinic business solution . . . . to cardiologists and hospitals. [And that Medtronic] [s]ales representatives were trained to show cardiologists how the physicians could use Medtronic pre-printed medical forms and templates to run a heart failure clinic . . . ." (alterations to original)).

Turning to the third category, Relator Forney contends that she gave the government a variety of documents. These documents have been provided to the court as Exhibit 17 to Relator Forney's response in opposition to Medtronic's motion for summary judgment. Specifically, Relator Forney claims that she provided documents with bates numbers 1 through 152, 258 through 429, 458 through 784, and 1072 through 2274 to the government. *See* Relator Forney's Opp. to Medtronic's Mot. for Summ. J. Based on Public Disclosure Bar at Ex. 17, Doc. No. 69-19. Relator Forney submitted a sworn declaration affirming that these documents were provided to the government prior to the commencement of this litigation. *See id.* at Ex. 16, Doc. No. 69-18.

Notwithstanding this declaration, Medtronic argues that the court should not consider these documents. *See* Tr. of Mot. for Summary J. at 60–61, Doc. No. 72. This is not a genuine dispute; Medtronic has offered no evidence indicating that these documents are not authentic or that Relator Forney did not actually provide them to the government. *See id.* By contrast, Relator Forney submitted evidence indicating that these documents are genuine (*i.e.*, the affidavit). *See* Forney's Opp. at Exs. 16, 17. Accordingly, the court finds that there is no genuine dispute that Relator Forney provided these documents to the government.

### 2. *Onwezen* and *Schroeder* are Valid Public Disclosures Because They are Federal Civil Hearings in Which the Government or its Agent is a Party.

As indicated above, the first inquiry is whether a valid prior public disclosure exists. Of the five cases identified by Medtronic, only two—*Onwezen* and *Schroeder*—satisfy the requirements of a public disclosure in section 3730(e)(4)(A). The other three *qui tam* cases do not qualify as valid prior public disclosures because the government declined to intervene in those cases.[4]

Section 3730(e)(4)(A)(i) requires government involvement in the prior case. Specifically, this section requires that "the Government or its agent" must have been a "party" in the prior case for the prior case to qualify as a public disclosure. *See* 31 U.S.C. § 3730(e)(4)(A)(i). Medtronic contends that the relator in a *qui tam* action is the Government's "agent." *See* Def. Medtronic, Inc.'s Reply Mem. in Further Supp. of its Mot. for Summ. J. at ECF pp. 6–7 ("Medtronic's Reply Br."), Doc. No. 70. According to Medtronic, because the government's "agent" was a party (*i.e.*, as the relator) the "Government or its agent [was] a party" in all five of the prior cases. *See id.* The court disagrees with this analysis.

Contrary to Medtronic's assertion, a *qui tam* relator is not the government's agent. To interpret the term "agent" the court looks to the text of the statute. The statute states: "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party . . . ." 31 U.S.C. § 3730(e)(4)(A)(i). The statute does not include any terms or context indicating agent should be given a meaning other than its ordinary one. The ordinary meaning of agent is "[s]omeone who is authorized to act for or in the place of another; a representative . . . ." Agent, Black's Law Dictionary (10th ed. 2014). An agency relationship

[4] The government declined to intervene in *Stokes*, *Doe*, and *Burns*. *See Stokes*, Notice of Election to Decline Intervention, Doc. No. 4 (filed Dec. 8, 2011); *Doe*, Notice of Election to Decline Intervention, Doc. No. 7 (filed June 17, 2016); *Burns*, Notice of the United States that it is not Intervening at this Time, Doc. No. 10 (filed Aug. 15, 2011).

> arises when one (a principal) manifests assent to another (an agent) that the agent will act on the principal's behalf, subject to the principal's control, and the agent manifests assent or otherwise consents to do so. An agent's actions have legal consequences for the principal when the agent acts within the scope of the agent's actual authority or with apparent authority, or the principal later ratifies the agent's action.

Agency, Black's Law Dictionary (10th ed. 2014). "The basic theory of the agency device is to enable a person, through the services of another, to broaden the scope of his activities and receive the product of another's efforts, paying such other for what he does but retaining for himself any net benefit resulting from the work performed." *Id.* (quoting Reuschlein & William A. Gregory, The Law of Agency and Partnership § 1, at 3 (2d ed. 1990)).

With this definition and explanation in mind, a relator in a *qui tam* suit does not appear to be the government's agent. First, there is no indication that the government has authorized the relator to act in its place as a representative. 31 U.S.C. § 3730(b)(1) provides that "[a] person may bring a civil action for a violation of section 3729 for the person and for the United States Government." 31 U.S.C. § 3730. That section does not employ the term "agent." Moreover, the statute does not "manifest[] assent to another (an agent) that the agent will act on the principal's behalf . . . ." Agency, Black's Law Dictionary (10th ed. 2014). The statute authorizes the relator to bring the action *for the relator* and for the United States. In a typical agency relationship, the agent would bring the action *solely* for the principal. *See id.* (noting that in a typical agency relationship the "agent will act on the principal's behalf . . . .").

This analysis is bolstered by the Supreme Court's discussion of an analogous issue in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000). In *Vermont Agency*, the Court addressed the question of whether, and if so how, a *qui tam* relator has constitutional standing. *See id.* at 771. The Court considered whether the relator had standing as the "statutorily designated agent of the United States . . . ." *Id.* The Court held that

this option—standing on the basis of agency—was "precluded" because "the statute gives the relator himself an interest *in the lawsuit*, and not merely the right to retain a fee out of the recovery." *Id.* (emphasis in original). This analysis fits well with the definition of agent outlined above. In the typical agency relationship, an agent is paid a fee for his or her actions on behalf of the principal. The agent would not usually have an interest in the lawsuit, and the principal would "retain[] for himself any net benefit resulting from the work performed." Agency, Black's Law Dictionary (10th ed. 2014). Unlike the typical agency relationship, here the government does not pay a fee to the relator, and the relator has an interest in the outcome of the lawsuit. Also, rather than the government "retaining for [itself] any net benefit," the net benefit is split between the relator and the government. *See* 31 U.S.C. § 3730(d).

Additionally, in the typical agency relationship the agent "will act on the principal's behalf, *subject to the principal's control*." Agency, Black's Law Dictionary (10th ed. 2014) (emphasis added). But here, in cases where the government declines to intervene and the relator proceeds with the action on the government's behalf, the government *cannot* control the relator's actions. *See* 31 U.S.C. § 3730(c)(3) ("If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action."). *Cf.* 31 U.S.C. § 3730(c)(1) ("If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action."). In such cases, the government cannot tell the agent what to do, dictate a specific litigation approach, or even tell the relator to drop the lawsuit.[5] *See* 31 U.S.C. § 3730(c)(3). This is

[5] The court is aware that the statute still affords some protections to the government in cases when the government declines to intervene. *See, e.g.*, 31 U.S.C. §§ 3730(c)(3), (4), (5). The court is also aware that a district court in Alabama recently addressed this question and relied on those protective provisions to hold that a *qui tam* relator is the government's agent for purposes of the public disclosure bar. *United States ex rel. Gilbert v. Virginia Coll., LLC*, No. 15cv336, 2018 WL 1535291, at *7 (N.D. Ala. Mar. 29, 2018). While these provisions afford some protection, the court does not believe they offer the same level of control a principal would typically have or an agent. Consequently, the court reaches a different conclusion than *Virginia College*. That said, the court

markedly different from the typical agent to principal relationship where the principal would be able to control the agent's actions. *See* Agency, Black's Law Dictionary (10th ed. 2014). Yet, here, Congress has not provided the court with any reason to define agent in a way other than how that word is typically understood. This is strong evidence that a relator is not the government's agent for purposes of section 3730(e)(4)(A)(i).

These reasons are already sufficient to find that a relator is not the government's agent for purposes of section 3730(e)(4)(A)(i). There is, however, a final additional factor that also supports this determination. In the typical agency relationship, the agent owes the principal various fiduciary duties. *See Basile v. H & R Block, Inc.*, 761 A.2d 1115, 1120 (Pa. 2000) ("An agency relationship is a fiduciary one, and the agent is subject to a duty of loyalty to act only for the principal's benefit." (citation and internal quotation marks omitted)). For example, in Pennsylvania a principal can bring a lawsuit for breach of a fiduciary duty owed to the principal by its agent. *See* Pennsylvania Suggested Standard Civil Jury Instructions, § 6.210, Breach of Fiduciary Duty—Elements of the Cause of Action (2015) ("An agent is required to act with the utmost good faith in carrying out the interests of his or her principal."). Thus, if the agent does not act with the "utmost good faith in carrying out the interests of his or her principal" he or she is subject to a lawsuit. The court is aware of no case or law indicating that a relator is subject to a lawsuit by the United States if he or she does not pursue the *qui tam* action with the "utmost good faith." For these reasons, the court determines that a relator is not the government's agent for purposes of the public disclosure bar.

Applying this determination to the putative public disclosures identified by Medtronic, neither the government nor an agent of the government intervened in *Burns*, *Stokes*, and *Doe*. In

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acknowledges that this is a difficult issue. The district court's well-reasoned opinion in *Virginia College* highlights this difficulty and persuasively presents the arguments on the opposing side.

*Burns*, *Stokes*, and *Doe*, Medtronic's best chance of satisfying the "Government or its agent is a party [to the action]" requirement was convincing the court that a *qui tam* relator is an agent. *See* Medtronic's Reply Br. at ECF pp. 6–7. Because the court has determined that a *qui tam* relator is not the government's agent, *Burns*, *Stokes*, and *Doe* do not qualify as prior public disclosures. Of the five putative prior public disclosures Medtronic identifies, the government only intervened in *Onwezen* and *Schroeder*.

Unfortunately, the court's analysis on the "government involvement" requirement is not yet complete. Relator Forney has raised another objection. In *Onwezen* and *Schroeder*, the government only intervened in part. Because of this, Relator Forney contends that the government should only be considered to be a "party" to the portion of the lawsuits in which the government *actually* intervened. *See* Forney's Br. at 14 ("[T]he United States intervened in part and thus is a party to those portions of the complaints, which may be able to be viewed as qualifying public disclosures under the amended public disclosure bar."). This argument is unpersuasive.

The issue here is whether the government becomes a "party" to the entire case when it intervenes in part. The answer is yes: When the government intervenes in a *qui tam* FCA case, the government becomes a party to the *entire* case, even if it is only pursuing some of the claims. *See United States ex rel. Estate of Gadbois v. PharMerica Corp.*, 292 F. Supp. 3d 570, 580 (D.R.I. 2017) (holding for purposes of an analogous provision—31 U.S.C. § 3730(e)(3)—that the government was a "party" in a prior case, notwithstanding that government only intervened in some of the claims); *United States ex rel. Bennett v. Biotronik, Inc.*, No. 14cv2407, 2016 WL 1587215, at *6–7 (E.D. Cal. Apr. 20, 2016) (same). For one, section 3730(e)(4)(A)(i) does not distinguish between situations where the government intervenes on all the claims alleged in the

relator's complaint and those where the government intervenes only as to certain claims. *See Biotronik*, 2016 WL 1587215, at *6 (highlighting this aspect of the statute in section 3730(e)(3)). Thus, the statute appears to set up an "all or nothing" situation: either the government was a party in the prior case or it was not. Applying this to the situation at hand, it is difficult to conceptualize how the government could intervene in part, but not be a party to the case. It seems far more likely that the government should be considered a party to the entire action, for purposes of this provision, even if the government has only intervened as to some of the claims.

The structure of the statutory provisions governing how and when the government may intervene also support this conclusion. When the government intervenes, it gains control over the action. *See* 31 U.S.C. § 3730(c)(1) ("If the Government proceeds with the *action*, it shall have the primary responsibility for prosecuting the action . . . ." (emphasis added)). It would be quite odd if the government could gain control over an action to which it was not a party. Additionally, "[t]he relevant FCA provisions [] refer to the 'action' and not theories[,] allegations," or claims. *Biotronik*, 2016 WL 1587215, at *7 (alterations to original); *see* 31 U.S.C. § 3730(b)(2) ("The Government may elect to intervene and proceed with the *action* . . . ." (emphasis added)). In sum, the government is a party to the action for purposes of 3730(e)(4)(A)(i) even if it only intervened on some of the claims.

To summarize the analysis up to this point, *Burns*, *Doe*, and *Stokes* do not satisfy the government-involvement requirement because the government did not intervene and a *qui tam* relator is not the government's agent. The government intervened in *Onwezen* and *Schroeder*, but it only intervened in part. Nonetheless, the government's partial intervention was sufficient to satisfy the "party" to the prior case requirement. Thus, *Onwezen* and *Schroeder* satisfy the government-involvement requirement.

After concluding that *Onwezen* and *Schroeder* satisfy the government-involvement requirement, the court must consider whether they satisfy the remaining statutory requirement to qualify as prior public disclosures. Specifically, *Onwezen* and *Schroeder* must constitute "Federal criminal, civil, or administrative hearing[s] in which the Government or its agent is a party . . . ." 31 U.S.C. § 3730(e)(4)(A). Relator Forney contends that neither *Onwezen* nor *Schroeder* satisfy the "civil hearing" requirement in the statute. *See* Forney's Br. at 16 ("[C]omplaints that are never served or litigated should not be considered the equivalent of civil hearings." (capitalization changed and emphasis removed)). According to Relator Forney, *Onwezen* "was dismissed the very day it was unsealed" and *Schroeder* "was subsumed within the Onwezen settlement, and was [] dismissed voluntarily without any further litigation." *Id.* (alteration to original). In short, Relator Forney argues that because neither of these cases involved extensive public litigation (or "hearings"), they do not satisfy this requirement.

Relator Forney's argument on the meaning of "civil hearing" is unavailing. As it relates to this issue, the "civil hearing" language was not meaningfully changed in 2010 when Congress amended the statute as part of the Patient Protection and Affordable Care Act ("PPACA"). *Compare* 31 U.S.C. § 3730(e)(4)(A) (pre-PPACA version—covering "disclosure of allegations or transactions in a criminal, civil, or administrative hearing . . . ."), *with* 31 U.S.C. § 3730(e)(4)(A) (post-PPACA version—covering disclosures in a "Federal criminal, civil, or administrative hearing in which the Government or its agent is a party . . . . "). Under the pre-PPACA language, the Third Circuit held that a complaint filed in civil litigation satisfies the "civil hearing" requirement. *See U.S. ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334 (3d Cir. 2005) ("[W]e are persuaded that a complaint in a civil action falls into the context of 'criminal, civil, or administrative hearings' and is sufficiently public within the meaning of the Act to

constitute a public disclosure."). The court sees no reason to depart from the Third Circuit's well-reasoned interpretation of the term "civil hearing" as it relates to whether a complaint filed in civil litigation is sufficiently public to satisfy the "civil hearing" requirement. Thus, both *Onwezen* and *Schroeder* satisfy the "civil hearing" requirement and they both qualify as prior public disclosures under the post-PPACA public disclosure bar.

### 3. With the Exception of Her Credentialing Allegation, the Prior Public Disclosures Disclosed Substantially the Same Fraud Alleged by Relator Forney.

Now that the court has determined *Onwezen* and *Schroeder* qualify as prior public disclosures, the next question is whether "substantially the same allegations or transactions as alleged in [this] action or claim were publicly disclosed" in *Onwezen* and *Schroeder*. 31 U.S.C. § 3730(e)(4)(A). In applying this provision, the Third Circuit has explained:

> "An allegation of fraud is an explicit accusation of wrongdoing. A transaction warranting an inference of fraud is one that is composed of a misrepresented state of facts plus the actual state of facts." Formulaically this appears as follows: "X (misrepresented state of facts) + Y (true state of facts) = Z (fraud)." A defendant must therefore show that substantially the same "allegation[ ]" of fraud (Z) *or* "transaction[ ]" of fraud (X + Y) was publicly disclosed through the sources enumerated in § 3730(e)(4)(A).

*U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 303 (3d Cir. 2016) (alterations in original) (emphasis in original) (internal citations omitted).

Here, Relator Forney's remaining allegations of fraud fall into two main categories: (1) free device checks and device interrogations, and (2) free practice management consulting.[6] In

[6] Medtronic breaks Relator Forney's practice management consulting theory into three allegations of fraud: practice management, reimbursement guidance, and administrative assistance. Medtronic's Br. at ECF pp. 17–19. The court has not included a third "practice management" allegation because it is redundant of administrative assistance and reimbursement guidance. In other words, the court has searched the second amended complaint and cannot locate an allegation of fraud that would fall into a third "practice management" allegation that does not already fall under either administrative assistance or reimbursement guidance.

As a side note, this does not meaningfully change the analysis. If the court created a third "practice management" allegation, the same disclosures that bar the administrative assistance allegation and/or the reimbursement guidance allegation would still serve as a bar. And similarly, it would be excepted from dismissal because Relator Forney is an original source on both of those allegations.

her device check theory, Relator Forney alleges that Medtronic is paying health care providers kickbacks in the form of free device checks and interrogations. As part of her device check theory, Relator Forney contends that Medtronic pays to have its representatives credentialed, which is a cost the health care provider would have to bear if Medtronic was not covering it.

Relator Forney's free practice management consulting theory contains two distinct allegations of fraud: fraud in the form of free reimbursement guidance and fraud in the form of free administrative work. In her reimbursement guidance theory, Relator Forney alleges that Medtronic is paying medical providers kickbacks in the form of reimbursement guidance. In her administrative work theory, Relator Forney argues that Medtronic is paying medical providers kickbacks in the form of free administrative work and consulting. The court will address each allegation of fraud in turn.

Beginning with her device check theory, Relator Forney contends that Medtronic trained clinical specialists to provide "checks" or "interrogations" of devices. *See* Second Am. Compl. at 9–10. This theory was disclosed in *Onwezen*. As noted above, the relator in *Onwezen* alleged as follows:

> As part of its efforts to corner the market, [Medtronic] promises both doctors and hospitals that use Medtronic's cardiac rhythm devices that it will provide all follow-up care for those patients. Physicians often complain that checking the devices during their clinic times is time-consuming and expensive. As an incentive for doctors and hospitals to choose Medtronic devices, Medtronic Representatives tell doctors and hospitals that if they use a Medtronic device, they will not have to be involved in any of the patient's follow-up care. . . .
>
> [T]he implant of a Medtronic pacemaker or ICD is often the first and last time the implant patient will ever see the doctor. Instead nearly all follow-up visits, any telephone or other inquiries, and necessary adjustments or programming changes to the device, and medical questions will all be handled by a Medtronic Representative . . . .

Def.'s Mot. at Ex. E at ¶¶ 68, 70 (alterations to original). *Onwezen* also alleged that this conduct amounted to fraud under the FCA. *See id.* at ¶¶ 110-17. While the allegation in *Onwezen* is broader than the allegation here (*i.e.*, *Onwezen* alleged that Medtronic provided all follow-up care and Relator Forney alleged that Medtronic provided follow-up care in the form of device checks and interrogations), the court is satisfied that the fraud allegation in *Onwezen* is substantially the same as the device check fraud allegation here. Consequently, the court will later consider whether Relator Forney is an original source as to this allegation.

Relator Forney also contends that, in order to facilitate these free "device checks," Medtronic had to pay to credential its clinical specialists. According to Relator Forney, Medtronic paid all the costs associated with credentialing, including background checks. She also alleges that "even separate and apart from the free services themselves, each Medtronic payment for credentialing constitutes a separate kickback to the health care provider that received – for free – a credentialed Clinical Specialist." Second Am. Compl. at 11. Medtronic has not identified, nor has the court been able to locate, a similar allegation of fraud in either *Onwezen* or *Schroeder*. Consequently, Relator Forney's "credentialing" allegation of fraud is not barred, and the court need not consider whether Relator Forney is an original source as to this allegation.

Turning to allegations of fraud relating to Relator Forney's practice management theory, Relator Forney contends that Medtronic—through a program called "*lean sigma*"—taught its employees how to provide free consulting services and that these free consulting services amounted to kickbacks. Relator Forney has disclosed two allegations of fraud under this umbrella theory: (1) Medtronic provided free reimbursement guidance; and (2) Medtronic provided free administrative assistance.

Relator Forney's allegation that Medtronic was paying kickbacks in the form of free reimbursement counseling was publicly disclosed in both *Onwezen* and *Schroeder*. Relator Forney contends that "Medtronic taught health care providers to increase profits by maximizing their revenue from government-funded health care programs." *Id.* at 12. In other words, "Medtronic provided free consulting to help health care providers maximize reimbursement from government-funded health care programs." *Id.* Both *Onwezen* and *Schroeder* alleged that Medtronic was providing free reimbursement consulting. In *Onwezen*, the relator contended that "Medtronic Representatives are trained to sit down with the doctor to show him how s/he is under-billing. They are instructed to point out to doctors that, in order to maximize profits, they should turn over all billing responsibilities to a Medtronic Representative." Def.'s Mot. at Ex. E at ¶ 75. Similarly, in *Schroeder*, the relator argued that "Medtronic [] directed sales representatives to educate physician staffs on how to bill Medicare, Medicaid and other insurers, in effect offering unpaid work from Medtronic employees to doctor's offices." Def.'s Mot. at Ex. I at ¶ 51 (alteration to original). Because these allegations of fraud are substantially the same as Relator Forney's reimbursement counseling allegation, the court will have to consider whether Relator Forney is an original source on this allegation.

Likewise, Relator Forney's allegation that Medtronic paid kickbacks in the form of free administrative work was disclosed in *Onwezen*. Relator Forney claims that "Medtronic [] directed its employees to engage in [] clerical data entry tasks as a means of providing value to the hospitals." Second Am. Compl. at 12 (alterations to original). As an example, Relator Forney contends she drafted a "Remote Follow – Up Worksheet" to health care providers so they could "track remote monitoring." *Id.* at 11. In *Onwezen*, the relator claimed that "Medtronic Representatives advise doctors that the Representatives will handle all of the paper- work [sic]

related to billing for implant patients, including filling out the 'visit sheets' used by doctors to document the work they have purportedly done, and the 'billing sheets' submitted to Medicare." Def.'s Mot. at Ex. E at ¶ 79. While the specific "data entry" examples Relator Forney gives are different than those disclosed in *Onwezen* (*e.g.*, Relator Forney points to remote monitoring worksheets, and the relator in *Onwezen* identified billing sheets), the substance of the fraud allegation is the same: Medtronic was providing kickbacks in the form of free administrative work that, if not for Medtronic, the health care provider would have otherwise had to do it.[7]

Additionally, *Schroeder* alleged that Medtronic was providing free consulting services to health care providers. See Def.'s Mot. at Ex. I at ¶ 81. Specifically, *Schroeder* alleged that Medtronic provided a "'turn-key' heart failure clinic business solution . . . to cardiologists and hospitals." *Id.* *Schroeder* also alleged that Medtronic "[s]ales representatives were trained to show cardiologists how the physicians could use Medtronic pre-printed medical forms and templates to run a heart failure clinic . . . ." *See id.* (alterations to original). This allegation is substantially similar to Relator Forney's allegation that Medtronic provided free administrative assistance in the form of free consulting services. *See* Second Am. Compl. at 13 ("Medtronic created an entire structure of 'lean sigma' training that taught Ms. Forney and others how to provide free consulting services as a means to integrate their services into the health care provider's practice management tasks."). Accordingly, the court will consider whether Relator Forney is an original source for her administrative assistance allegation of fraud.

In sum, *Onwezen* and *Schroeder* disclosed all of Relator Forney's remaining allegations of fraud except for her credentialing allegation. Accordingly, the court will consider whether Relator Forney is an original source on her (1) device check allegation of fraud, (2)

[7] The court notes, however, that even if the allegation of fraud here was not substantially similar to the fraud alleged in *Onwezen*, the overall outcome would be the same as the court ultimately concludes that Relator Forney is an original source as to all of her barred allegations of fraud.

reimbursement counseling allegation of fraud, and (3) administrative assistance allegation of fraud.

#### 4. Relator Forney is an Original Source Because She Materially Adds to the Publicly Disclosed Allegations of Fraud.

The public disclosure bar provides that the court shall dismiss the action if a prior public disclosure disclosed substantially the same allegation of fraud *unless* "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). Under the statute, there are two ways a relator can qualify as an original source; an original source is

> an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(B). There is no contention that Relator Forney provided the government with information prior to the complaints in *Onwezen* and *Schroeder*. Consequently, the first option is not at issue here, and the only applicable exception is the second one, *i.e.*, whether Relator Forney "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and [] has voluntarily provided the information to the Government before filing an action under this section." *Id.* (alteration to original).

In *Moore*, the Third Circuit elaborated on this definition. Specifically, in *Moore* the Third Circuit noted that the inquiry is twofold: (1) is the information independent of the prior public disclosures? And (2) does the relator's information "materially add" to the information revealed through the prior public disclosures? *See* 812 F.3d at 304–08. Here, Medtronic does not dispute that the information Relator Forney provided to the government is independent of the prior public disclosures. *See* Medtronic's Reply Br. at ECF p. 14 ("Medtronic's argument is that

the information Relator gave to the government in advance of filing her case did not materially add to the extensive public disclosures, not that she copied information from these earlier complaints."); *see also* Tr. at ECF p. 59 ("[Relator Forney] has a statement in her declaration that she never saw the complaints before she saw our summary judgment. We're not contesting that." (alteration to original)). Thus, the court will only consider whether the information materially adds to the prior public disclosures.

In *Moore*, the Third Circuit held that to materially add "to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." 812 F.3d at 306. Said another way, "a relator materially adds to the publicly disclosed allegation or transaction of fraud when it contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: the who, what, when, where and how of the events at issue." *Id.* (internal quotation marks and citation omitted). Here then, the court must consider whether Relator Forney improves the quality of the prior public disclosures by providing the "who, what, when, where and how of the events at issue." *Id.* (internal quotation marks omitted).

In its supplemental brief, Medtronic attempts to frame this as a "'rigorous' requirement" that hinges on a determination of whether the information provided "would have a 'natural tendency to influence' the Government's decisions." Def. Medtronic, Inc.'s Suppl. Mem. in Further Supp. of Its Mot. for Summ. J. at ECF p. 9 ("Medtronic's Suppl. Br."), Doc. No. 76. To support this argument, Medtronic cites a Supreme Court case, *Universal Health Services, Inc. v. United States*, 136 S. Ct. 1989 (2016), and a First Circuit case, *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201 (1st Cir. 2016). Medtronic's reliance on these cases is

unavailing: *Universal Health* is distinguishable and *Winkelman* is not binding on this court. Beginning with *Universal Health*, there the Supreme Court was interpreting the meaning of "material" as an element of a fraud claim under 31 U.S.C. § 3729(a)(1). *See* 136 S. Ct. at 1995. The Court held that for something to be material, it must be of such importance that it influences the decision maker. *See id.* at 2002. The Court further opined that this is a "rigorous requirement." *See id.*

Medtronic has attempted to argue that the Supreme Court's interpretation of "material" in section 3729(a)(1) governs the court's interpretation of "materially adds" in section 3730. Medtronic's Suppl. Br. at ECF pp. 8–9. Medtronic acknowledges that the Court's interpretation of "material" in *Universal Health* was in a different context, but believes that it should nonetheless govern because materiality is a unitary concept. *See id.*; *Universal Health*, 136 S. Ct. at 2002; *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 763 (3d Cir. 2017). This argument is facially appealing, but ultimately not persuasive.

When the Supreme Court and the Third Circuit treated "materiality" as a unitary concept, both courts were attempting to determine whether the common law conception of "materiality" as part of a fraud claim should govern or whether the statute's definition of materiality as an element of fraud under the FCA should govern. *See Universal Health*, 136 S. Ct. at 2002; *CVS Caremark Corp.*, 875 F.3d at 763. Both courts agreed that they did not need to answer this question because "materiality" as an *element of fraud* is a unitary concept. *See Universal Health*, 136 S. Ct. at 2002; *CVS Caremark*, 875 F.3d at 763. In the fraud context, materiality is weighed and analyzed on the basis of its importance to the fraud victim. *See Universal Health*, 136 S. Ct. at 2002. In that sense, it is always a "unitary" concept—regardless of whether it is part of an FCA fraud claim or a common law fraud claim. *See id.*

Here, however, "materially" in section 31 U.S.C. § 3730(e)(4)(B) is not being considered as an element of a fraud claim. Consequently, the Supreme Court's interpretation of materiality in *Universal Health* has little bearing on this court's interpretation of "materially adds" in section 3730.

Even though "material" as an element of fraud and "materially adds" as part of the original source analysis are two different concepts, the First Circuit in *Winkelman* applied *Universal Health*'s definition of material to the original source question. *See* 827 F.3d at 211. Not surprisingly, Medtronic contends that this court should follow the decision in *Winkelman*. *See* Medtronic's Suppl. Br. at ECF p. 9. To bolster its position, Medtronic highlights that *Universal Health* was decided after *Moore* and before *Winkelman*. *Winkelman* thus had the advantage of the decision in *Universal Health*, whereas *Moore* did not.

Despite *Winkelman*'s temporal advantage, the court is not persuaded by it for the following reasons: First, the *Winkelman* panel did not have to apply the *Universal Health* definition of material. As explained above, the panel was not bound to follow *Universal Health*'s definition of material in the context of the original source exception. Second, the First Circuit did not provide a reason why it applied *Universal Health* to the original source exception. *See Winkelman*, 827 F.3d at 211. That lack of justification is particularly noticeable in light of the fact that the First Circuit did not have to apply *Universal Health*. And third (and most importantly), this court is bound by the Third Circuit's decision in *Moore*. *Moore* and *Winkelman* apply two different standards: *Moore* adopted a relatively broad definition of materiality, *see* 812 F.3d at 306, while *Winkelman* adopted the narrower definition from *Universal Health*, *see* 827 F.3d at 211. In the absence of controlling precedent compelling a

contrary conclusion—and *Universal Health* does not compel a contrary conclusion here—the court is bound by the Third Circuit's decision in *Moore*.

Thus, the relevant standard is whether the relator "contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: the who, what, when, where and how of the events at issue." *Moore*, 812 F.3d at 306 (citation and internal quotation marks omitted). Relator Forney contends that the information she provided to the government added to the "who, what, when, where and how of the events at issue." Relator Forney's Suppl. Mem. in Opp. to Medtronic's Mot. for Summ. J. at 7 ("Forney's Suppl. Br."), Doc. No. 75.

Beginning with her device check theory, Relator Forney points the court to a series of records documenting Medtronic representatives providing device checks to patients at various health care providers. *See id.* at 8–10. For the most part, these documents include the name of the Medtronic representative, the date and time when the device check was performed (to be precise, when the device check was scheduled to be performed), the name of the patient, and the name and location of the health care provider. *See* Relator Forney's Opp. to Medtronic's Mot. for Summ. J. Based on Public Disclosure Bar at Ex. 17 at 1249–417, 2253–74 ("Ex. 17") (this exhibit is not on ECF). Relator Forney's characterization of these documents is fair; these documents do describe and document device checks that Medtronic representatives performed.

Medtronic contends that Relator Forney's provisions of names, places, and times (here and elsewhere) does not help her achieve original source status because the prior public disclosures were broad enough that they included these people, places, and times. Specifically, Medtronic alleges that

> According to *Onwezen*, the principal players in this scheme—the "who," as *Moore* puts it—were Medtronic's entire field sales force. (*See* Onwezen Compl.

> ¶¶ 8, 68, 78-82, Ex. E, ECF No. 64). The "where" was nationwide. (*See id.*) The "when" was an ongoing practice dating back more than a decade and continuing into the foreseeable future. (*Id.* at ¶¶ 3, 76). The mechanics of the alleged scheme—the "what" and the "how"—was to offer a comprehensive, soup-to-nuts process of handling all post-implant follow-up care, billing, and paperwork for all implanted devices. (*Id.* at ¶¶ 8, 70).
>
> Nothing Relator disclosed to the government before filing suit materially adds to the picture of the alleged scheme painted by the *Onwezen* complaint.

Medtronic's Suppl. Br. at ECF pp. 11-12 (emphasis in original). Medtronic is correct that the allegations in *Onwezen* were broad, sweeping, and general. *Moore*, however,—like Rule 9(b)—places an emphasis on the *details* the relator adds to the factual background possessed by the government. *See* 812 F.3d at 306. This rationale is easy to understand: More detailed information is usually better information than broad, sweeping, general allegations, such as the ones in *Onwezen*. It is incongruous to think that *Moore*—with this heavy emphasis on details—could have meant for a single sentence allegation, framed in the broadest, most general terms possible (such as the allegations in *Onwezen*), to bar a subsequent disclosure containing thousands of pages of details (such as the documents Relator Forney provided to the government in Exhibit 17).

That said, not all details satisfy the standard outlined in *Moore*. To satisfy the standard, the details must significantly add to the background already possessed by the government. *See id.* at 306. Thus, some details do not "significantly add" to the essential background information. Whether the details "significantly add" is a fact-intensive inquiry that involves weighing the prior public disclosures against the information relayed to the government in the present case.

Here, after reviewing the documents Relator Forney provided to the court that confirm and document Medtronic's practice of providing free device checks and interrogations, the court concludes that the information she provided to the government meaningfully adds to the prior

public disclosures. *See* Ex. 17 at 1249–417. The fact that the allegations in *Onwezen* were broad and the information Relator Forney has supplied here is detailed, specific, and helpful, is further support for this conclusion. *See id.* Consequently, the court finds that Relator Forney is an original source as to her device check allegation of fraud.

Turning to Relator Forney's practice management theory, Relator Forney contends that she provided the government with identities of Medtronic employees who worked as lean sigma consultants, "worksheets created for free by Medtronic," "data collected to provide lean sigma services," and examples of consulting given to local health care providers. *See* Forney's Suppl. Br. at 13. Here again, Relator Forney points to a variety of documents that included this information. *See, e.g.*, Ex. 17 at 1781–87, 471–84, 485–91, 494–503. The court has reviewed these documents and finds that while Relator Forney's characterization is exaggerated at points, these documents mostly deliver the information she contends they contain.

Relator Forney also contends that she added to the "what and how" by providing the government with Medtronic's "value based workbooks." *See* Forney's Suppl. Br. at 14–16. These workbooks allegedly describe and discuss Medtronic's strategy of convincing health care providers to purchase its products based on the free services it offers. *See id.*

Medtronic suggests three reasons as to why these manuals should not help Relator Forney achieve original source status. First, Medtronic argues that they are not helpful to Relator Forney because they are old. *See* Medtronic's Suppl. Br. at ECF p. 24. Specifically, one of the workbooks Relator Forney provides is from 2006 and the other is from 2008. *See id.* Second, Medtronic argues that these manuals are not helpful because they are benign. *See id.* at ECF p. 25 ("The VBS Workbooks reflect sales communication training, not a conspiracy to pay kickbacks." (capitalization altered)). Finally, Medtronic claims that Relator Forney takes

statements from the workbooks out of context. *See id.* at ECF pp. 26–29. Medtronic claims that when viewed in their proper context these statements have little, if anything, to do with Relator Forney's alleged fraudulent scheme. *See id.*

These arguments are ultimately unavailing. On the first argument, Medtronic states that there is "[n]othing in the materials that Relator provided to the Government indicat[ing] that these documents [*i.e.*, the value-based workbooks] were in use at any point after March 2010, which is as far back as the conduct at issue in this case extends." *Id.* at ECF p. 24 (alterations to original). But there is also nothing to indicate that they were not in use after March 2010. Moreover, even if Medtronic stopped using them before March 2010, they still provide details on the nature of its selling plan prior to 2010. Relator Forney's description of Medtronic's plan during the time period at issue here matches the service-based plan described in those workbooks. *Compare* Second Am. Compl. at 9 ("Medtronic intentionally focused on services that would lower the practice costs incurred by hospitals and health care providers. Indeed, Medtronic trained all its Clinical Specialists to engage in discussions about practice overhead with health care providers."), *with* Ex. 17 at 1966 (outlining a similar approach). Thus, those workbooks are—at the very least—corroborating evidence that add details to the factual background possessed by the government based on the prior public disclosures.

On the second argument, Medtronic believes that the information in these materials is harmless, *i.e.*, it is not evidence of a fraudulent scheme. Medtronic's Suppl. Br. at ECF pp. 25–26. In other words, Medtronic essentially repeats its argument from its motion(s) to dismiss that Relator Forney's allegations of fraud are not actionable. *See* Def. Medtronic, Inc.'s Mem. of Law in Supp. of Its Mot. to Dismiss at ECF p. 8, Doc. No. 30-1. Unfortunately, courts in this circuit do not address whether the alleged fraud is actionable in a motion based on the public

disclosure bar. *See Moore*, 812 F.3d at 297 ("At issue on appeal is *not* whether Moore has alleged an actionable fraud." (emphasis in original)). Consequently, this argument has minimal legal significance.

Medtronic's arguments are nonetheless understandable. Part of what gives Medtronic's motion (and subsequent briefing) force—and what makes the decision on this issue difficult—is that the actions Relator Forney alleges were fraudulent appear somewhat benign. As the court noted when it ruled on Medtronic's second motion to dismiss, "the court is concerned that the relator's theory of support services amounting to illegal remuneration will not ultimately prove to be viable." Aug. 14, 2017 Order, Doc. No. 52. But whether the alleged fraud is actionable is not an appropriate consideration with respect to this motion.

Finally, in its third argument Medtronic contends that Relator Forney has taken statements from the workbook out of context. For example, she alleges that the workbooks told employees to "tell health care providers about the disadvantages of focusing on price when making decisions about medical devices." Forney's Suppl. Br. at 14 (citation and internal quotation marks omitted). Medtronic disagrees with Relator Forney's characterization and contends that the real point of this exercise was to teach Medtronic Representatives that they should not focus solely on price when marketing products. *See* Medtronic's Suppl. Br. at ECF p. 28. "Rather, Medtronic representatives are to use their expertise to recommend the right device for the right situation, which will save customers money over the long term." *Id.* Medtronic is partly correct. This exercise in the workbook stresses choosing the right device for the right situation, but it also stresses that Medtronic staff should be telling customers about how "less expensive products have fewer people to support them." Ex. 17 at 1966. And that the customer may "be unable to get the support it needs from a [different] supplier." *Id.* A reasonable

implication from this discussion is that Medtronic Representatives should stress how Medtronic will provide free services to the health care provider.

In short, the workbooks do not appear to be a smoking gun, but they do show that Medtronic had an extensive training plan in place that taught their sales force to emphasize non-price criteria when selling Medtronic products. In this sense then, the workbooks add to the factual background of the fraud by showing the "how" of this plan.

Next, Relator Forney contends she disclosed information on how "Medtronic provided advice on coding." Forney's Suppl. Br. at 19; *see* Ex. 17 at 1–110, 111–133, 270–328, 329–51, 352–406, 1161–235. The court has reviewed these documents and concludes that they provide significant details on how Medtronic implemented this scheme. These documents describe coding procedures Medtronic gave to physicians and hospitals. Most of them are training documents which were ostensibly shown to Medtronic Representatives, and/or hospitals and physicians. *See, e.g.*, Ex. 17 at 1-110. These presentations not only show how Medtronic gave advice, they show "what" advice Medtronic gave because they contain the exact coding advice Medtronic Representatives were providing. *See, e.g.*, *id.*

Considering the totality of the evidence that Relator Forney has provided regarding her reimbursement guidance and administrative work allegations of fraud, the court is satisfied that she qualifies as an original source. Relator Forney's vast supply of names, places, times, and strategies significantly add to the essential factual background possessed by the government from *Onwezen* and *Schroeder*.

## IV. CONCLUSION

In sum, Medtronic identified two valid prior public disclosures: *Onwezen* and *Schroeder*. *Onwezen* and *Schroeder* disclosed substantially the same allegations of fraud that Relator Forney

is pursuing here (with the exception of her allegation that Medtronic's credentialing payments constitutes a kickback). Notwithstanding the existence of these public disclosures and their substantial similarity to Relator Forney's allegations, she provided the government with extensive details of Medtronic's alleged fraudulent scheme. These extensive details significantly added to the essential factual background possessed by the government from *Onwezen* and *Schroeder*. Consequently, she is an original source as to her barred allegations of fraud and these claims survive dismissal under the public disclosure bar. The court will deny the motion in its entirety.

The court will enter a separate order.

BY THE COURT:

/s/ *Edward G. Smith*
EDWARD G. SMITH, J.